DENNIS L. KENNEDY
Nevada Bar No. 1462
JOSHUA M. DICKEY
Nevada Bar No. 006621
BAILEY❖KENNEDY
8984 Spanish Ridge Ave.
Las Vegas, Nevada 89148
Telephone: (702) 562-8820
Facsimile: (702) 562-8821
Email: jdickey@baileykennedy.com

REX A. LITTRELL (Admitted Pro Hac Vice)
ULMER & BERNE LLP
88 East Broad Street, Suite 1600
Columbus, Ohio 43215-3581
Telephone: (614) 229-0000
Facsimile: (614) 229-0001
Email: rlittrell@ulmer.com

JOSEPH P. THOMAS (Admitted Pro Hac Vice)
LINDA E. MAICHL (Admitted Pro Hac Vice)
TIFFANY REECE CLARK (Admitted Pro Hac Vice)
ULMER & BERNE LLP
600 Vine Street, Suite 2800
Cincinnati, Ohio 45202
Telephone: (513) 698-5000
Facsimile: (513) 698-5001
Email: jthomas@ulmer.com
lmaichl@ulmer.com
tclark@ulmer.com

Attorneys for Defendant PLIVA, Inc.

UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

MARY KAREN MORETTI, Plaintiff, v. PLIVA, INC., and TEVA PHARMACEUTICALS, USA, INC., Defendants.	CASE NO. 2:08-CV-00396-JCM (CWH)

ORDER GRANTING DEFENDANT PLIVA, INC.'S MOTION TO DISMISS [DOC.271]

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This matter came before the court on defendant PLIVA, Inc.'s motion to dismiss [doc. 271]. The motion was fully briefed by the parties, and an oral hearing was conducted by the Court on December 5, 2011. After a review and consideration of the briefs, authorities, and the oral argument of counsel, the court grants the motion to dismiss for the reasons that follow.

Plaintiff's Claims and Procedural History

1. Plaintiff, Mary Karen Moretti, originally filed her complaint in the United States District Court for the District of Minnesota on September 7, 2007.

2. Plaintiff's original complaint alleges that she suffered injuries as a result of ingesting the drug metoclopramide manufactured by various named defendants, including defendant PLIVA, Inc.

3. The original complaint also asserted liability against the manufacturers of the brand name version of metoclopramide, Schwarz Pharma, Inc. ("Schwarz") and Wyeth, Inc. ("Wyeth"), although plaintiff did not ingest metoclopramide manufactured by those entities.

4. Defendants subsequently answered and moved to transfer venue pursuant to 28 U.S.C. §1404. On March 17, 2008, the United States District Court for the District of Minnesota granted the motion. This court received the transfer on March 21, 2008.

5. Following transfer to this court, Wyeth and Schwarz moved for summary judgment on all claims asserted by plaintiff against them. On March 20, 2009, this court granted Wyeth and Schwarz's motion for summary judgment, and dismissed them from the action [doc. 148].

6. On June 23, 2009, plaintiff filed a second amended complaint [doc. 161]. In her second amended complaint (as in her original and first amended complaint), plaintiff asserts the following thirteen counts: (1) strict products liability (design defect and inadequate warnings),

(2) breach of express warranty, (3) breach of implied warranties, (4) negligence and gross negligence, (5) misrepresentation by omission, (6) constructive fraud, (7) violation of the Minnesota Deceptive Trade Practice Act, (8) violation of the Minnesota False Statement in Advertising Act, (9) violation of the Minnesota Prevention of Consumer Fraud Act, (10) intentional infliction of emotional distress, (11) negligent infliction of emotional distress, (12) negligent misrepresentation, and (13) fraud by concealment.

7. Although plaintiff's second amended complaint includes thirteen counts, each count is premised on the content of PLIVA's metoclopramide package insert.[1] All plaintiff's claims are premised on her allegations that the label accompanying the metoclopramide she ingested was false, misleading, or otherwise inadequate.

8. Specifically, plaintiff's second amended complaint contains numerous allegations that PLIVA failed to adequately warn, provided allegedly misleading information, and/or concealed information regarding the alleged risks of metoclopramide use, and each count contains an allegation or allegations relating to an alleged failure to warn, allegedly misleading information, or some alleged omission of information by PLIVA.

9. On June 23, 2011, the Supreme Court of the United States issued its opinion in *PLIVA, Inc. v. Mensing*, 564 U.S. ---, 131 S. Ct. 2567 (2011), *reh'g denied* 2011 WL 35557247 (U.S. Aug. 15, 2011) holding that state-law tort claims against generic drug manufacturers based on an alleged failure to warn are preempted by federal law.

10. On September 7, 2011, PLIVA filed its motion to dismiss [doc. 271] on the ground that plaintiff's claims are preempted by federal law as explained in *Mensing*.

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[1] This court previously held that plaintiff's claims for violations of Minnesota trade practice and consumer protection laws are not viable because they do not exist under Nevada law. (*See* Findings of Fact, Conclusions of Law and Judgment on Wyeth and Schwarz Pharma, Inc.'s Motion for Summary Judgment [doc. 148].)

11. On September 26, 2011, plaintiff filed her response in opposition to PLIVA, Inc.'s motion to dismiss [doc. 273] in which she argues that she has alleged theories of liability that survive the Supreme Court's decision in *Mensing*. Plaintiff contends that PLIVA had duties under federal law that it allegedly failed to perform. For instance, plaintiff claims that PLIVA had a duty under federal law to keep abreast of information and perform post-marketing surveillance regarding its drug product and to "take action (notifying the FDA and/or brand-name manufacturer) where there is evidence that its drug may be harming people."

12. Plaintiff also argued that PLIVA had a duty to "communicate existing warnings to the medical community," and that PLIVA had a variety of tools available by which it could have disseminated information to her and the medical community. Specifically, plaintiff asserts that PLIVA could have sent dear healthcare professional letters, conducted training programs, or utilized other communication methods to provide information regarding metoclopramide's alleged risks to her, her physician, and the medical community. Plaintiff asserts that claims based on a failure to employ those avenues of communication are not addressed by *Mensing*, and therefore, are not preempted.

13. In addition, plaintiff argued that she had a claim based on PLIVA's continued manufacture and distribution of its metoclopramide "despite the fact it [was] misbranded." According to plaintiff, PLIVA's metoclopramide was misbranded because it understated the risk allegedly associated with the product's use and lacked "adequate directions for use." Plaintiff argued that *Mensing* does not foreclose liability based on that alleged misbranding. Plaintiff also argued that PLIVA was required to remove its metoclopramide from the market for a period of time.

14. Finally, plaintiff also argued that *Mensing* does not preempt "any claim where the manufacturer could have satisfied its duty under state law by approaching FDA with information supporting a label change for metoclopramide, or by suspending sales of its drug."

15. In response to plaintiff's arguments, PLIVA argued that any "claims" based on its alleged failure to perform such alleged duties under the FDCA are not enforceable through a private right of action and that no state-law duty exists to perform those activities. PLIVA also argued that the activities plaintiff contends PLIVA failed to perform are merely activities that might eventually lead to a change in the product's labeling and are not stand-alone causes of action. PLIVA also pointed out there is no basis for plaintiff's argument that there was any requirement to remove PLIVA's metoclopramide product from the market at any time. In addition, PLIVA pointed out that plaintiff's argument that a claim based on an alleged failure to monitor a drug's safety, conduct post-marketing surveillance, and/or notify FDA and the brand-name manufacturer of safety information was addressed and rejected by the Court in *Mensing*.

16. PLIVA also argued that *Mensing* precludes plaintiff's argument that it could send dear healthcare professional letters or utilize other methods of communication as to do so would imply therapeutic differences between its generic version of metoclopramide and the brand-name version, Reglan.

17. In response to plaintiff's argument that she had a valid claim because PLIVA's metoclopramide was misbranded, PLIVA explained that whether or not a product is misbranded is a matter of federal law and the FDCA did not provide a private right of action. In addition, PLIVA argued that the misbranding issue was briefed, argued, and decided by the Court in *Mensing*. Specifically, PLIVA argued that the Supreme Court rejected FDA's premise that state-law claims are not preempted if the drug product is misbranded under federal law.

18. PLIVA argued that plaintiff's theory that her claims were not preempted because PLIVA could have suspended sales of the drug ignored the simple fact that a preemption analysis is not necessary where a product is not on the market. In addition, PLIVA argued Congress vested sole authority to decide whether or not drugs could be marketed in

interstate commerce in FDA and that a state-law jury cannot second guess FDA's risk-benefit analysis.

19. Finally, PLIVA argued that the decisions relied on by plaintiff involving express preemption provisions are not applicable because the Court's decision in *Mensing* is based on conflict preemption under the U. S. Constitution, and not an express preemption provision in a statute.

Standard for a Motion to Dismiss

20. A motion for judgment on the pleadings under Federal Rule of Civil Procedure 12(c) is governed by the same standard as a 12(b)(6) motion to dismiss. *See Cafasso v. General Dynamics C4 Systems, Inc.*, 637 F.3d 1047, 1055 n.4 (9th Cir. 2011). A Rule 12 motion should be granted when, viewing the alleged facts in the light most favorable to the plaintiff, the complaint fails to state a claim upon which relief may be granted. *See Bell Atl. Corp v. Twombly*, 550 U.S. 544, 570 (2008)). Although the court should accept as true all well-pleaded allegations and should view the complaint in a light most favorable to the plaintiff, the "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555.

21. In *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009), the United States Supreme Court articulated a two-step process for determining whether a complaint meets the standard to survive a motion to dismiss. First, a court must identify those allegations that, because they are no more than conclusions, are not entitled to the assumption of truth. *See id.* at 1951. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice," *id.* at 1951 (*citing Twombly*, 550 U.S. at 554-55), nor do "[f]ormulaic recitation[s] of the elements of [the] cause[s] of action" with no facts to support the claims. *Twombly*, 550 U.S. at 555; *Iqbal*, 129 S. Ct. at 1949. Second, the court should assume the truth of well-pleaded factual allegations, if the complaint contains any, and

determine whether they plausibly give rise to an entitlement to relief. *See Iqbal*, 129 S. Ct. at 1951. "Where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged – but has not 'show[n]' – 'that the pleader is entitled to relief,'" and, it, therefore, should be dismissed. *Id.* at 1950 (*quoting* Fed. R. Civ. P. 8(a)(2)).

***Mensing* and the Applicable Preemption Analysis**

22. In *Mensing*, the United States Supreme Court held that state-law tort claims against generic drug manufacturers based on an alleged failure to warn are preempted by federal law.

> These consolidated lawsuits involve state tort-law claims based on certain drug manufacturers' alleged failure to provide adequate warning labels for generic metoclopramide. The question presented is whether federal drug regulations applicable to generic drug manufacturers directly conflict with, and thus pre-empt, these state-law claims. We hold that they do.

Mensing, 131 S. Ct. at 2572.

23. As plaintiff does here, the plaintiffs in *Mensing* alleged that the generic drug company defendants had failed to adequately warn of the risks purportedly associated with the use of their products. *See Mensing* at 2573. The generic drug company defendants argued that the plaintiffs' state-law tort claims were preempted because, under federal law, generic drug manufacturers are not permitted to add warnings to or strengthen the labeling of their products without prior FDA approval. *See id.*

24. The plaintiffs in *Mensing* acknowledged that federal law requires generic drug labeling to be the same as the labeling of the reference listed drug ("RLD") upon which it is based to obtain approval. *See id.* at 2574. However, plaintiffs argued that the generic drug defendants could add warnings or strengthen the labeling after approval using FDA's CBE procedure, or by sending letters to health care professionals. *See id.* at 2575. In addition,

plaintiffs argued that the generic drug company defendants could, at a minimum, approach FDA in an effort to effect a change to the product's labeling. *See id.* at 2576.

25. The Supreme Court analyzed the plaintiffs' state-law claims against the generic drug company manufacturers – substantively the same failure-to-warn claims alleged here – and found them preempted by federal law. The Supreme Court disagreed with the plaintiffs' argument that federal law did not conflict with, and thus preempt, their state-law claims.

> We find impossibility here. It was not lawful under federal law for the Manufacturers to do what state law required of them. And even if they had fulfilled their federal duty to ask for FDA assistance, they would not have satisfied the requirements of state law.

Id. at 2577-78.

26. The Supreme Court specifically found that if generic drug companies change their labeling to satisfy a state-law duty to warn, they violate federal law. *See id.* at 2578. The Supreme Court accepted FDA's interpretation of its own regulations and concluded that generic drug companies cannot use the CBE process to unilaterally strengthen their warnings and cannot send "dear doctor" letters to provide additional warnings to physicians. *See id.* at 2575-76. The Supreme Court also concluded that the mechanism FDA identified by which generic drug companies purportedly could achieve a change in the warnings, *i.e.*, to propose or ask FDA for assistance in changing the warnings, would not have satisfied any state tort-law duty to provide adequate labeling. *See id.* at 2578.

27. *Mensing* is the controlling preemption decision applicable to personal injury cases, such as plaintiff's case here, against generic drug manufacturers, such as PLIVA.

28. Plaintiff's argument that the preemption analysis in this case is or should be governed by various decisions of the United States Supreme Court and the Ninth Circuit Court of Appeals involving express preemption provisions such as *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992); *Altria Group, Inc., Inc v. Good*, 555 U.S. 70 (2008); *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431 (2005); and *Rivera v. Phillip Morris, Inc.*, 395 F.3d 1142 (9th

Cir. 2005), is misplaced. The issue here does not involve an express preemption provision. The Supreme Court in *Mensing* found claims, like plaintiff's here, preempted under conflict preemption principles. As a result, cases analyzing express preemption provisions are inapplicable.

Plaintiff's Claims Are Preempted

29. This court has carefully reviewed and considered the memoranda filed by PLIVA and plaintiff in support of and against PLIVA's motion to dismiss and the arguments of counsel at the hearing on December 5, 2011. Based upon that review and consideration, PLIVA's motion shall be granted.

30. Applying *Mensing*, plaintiff's claims are preempted and must be dismissed. Despite being pled as numerous different causes of action, at their core, all plaintiff's claims arise from plaintiff's allegations that the content of PLIVA's metoclopramide labeling either was false, misleading, or inadequate. None of the arguments advanced by plaintiff change the preemption analysis.

31. The Supreme Court made clear in *Mensing* that state-law tort claims based on a generic drug manufacturer's labeling conflict with, and thereby are preempted by, federal law. *Mensing*, 131 S. Ct. at 2572. Under the federal regulations applicable to generic drug manufacturers such as PLIVA, PLIVA could not unilaterally change its metoclopramide labeling. Therefore, a direct, positive conflict exists between state-law tort claims that involve a generic drug's labeling and the federal law governing generic drug products. *Id.* at 2575-76, 2578.

32. The court rejects plaintiff's characterization of *Mensing*'s holding as a "narrow one" not applicable to her claims in this case. Both the majority and the dissenting justices in *Mensing* acknowledged the broad scope of the decision requiring the dismissal of such lawsuits against generic drug manufacturers. *Id.* at 2581 (Thomas, J., for the majority) ("federal law

preempts these lawsuits"); *Id.* at 2592 (Sotomayor, J., for the dissenters) (a person taking a generic drug "has no right to sue").

33. The court rejects plaintiff's arguments that she has claims that survived *Mensing* based on (1) PLIVA's alleged manufacture and continued distribution of a "misbranded" drug in violation of federal law, (2) PLIVA's alleged failure to conduct post-marketing surveillance or report adverse events, or (3) PLIVA's "failure to communicate" warnings about metoclopramide by "tools" other than the labeling for metoclopramide.

34. Numerous other courts have rejected those same arguments and dismissed lawsuits against generic drug manufacturers. *See, e.g.*, *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011), *petition for reh'g en banc denied* (6th Cir. Nov. 22, 2011) (rejecting similar post-*Mensing* arguments by plaintiffs and affirming dismissal of claims against generic drug manufacturers); *Mensing v. Wyeth, Inc.*, No. 08-3850, 2011 WL 4636653 (8th Cir. Sept. 29, 2011) (denying motion to file supplemental briefing raising similar post-*Mensing* arguments and affirming dismissal of claims against generic drug manufacturers); *Gross v. Pfizer Inc.*, No. 10-cv-110-AW (D. Md. Nov. 22, 2011) (rejecting similar post-*Mensing* arguments by plaintiff and dismissing all claims against generic drug manufacturer as preempted by *Mensing*); *In re: Fosamax (Alendronate Sodium) Prods. Liab. Litig. ("Fosomax")*, MDL No. 2243, Civ. No. 08-008 (D.N.J. Nov. 21, 2011) (MDL decision dismissing all plaintiffs' claims against all generic drug manufacturers for defective manufacture; defective design; failure to warn; negligence; fraud, misrepresentation, and failure to conform to representation, negligent misrepresentation; breach of express warranty; breach of implied warranty; violation of consumer protection laws; restitution, and loss of consortium as preempted under *Mensing*); *Morris v. Wyeth, Inc.*, 2011 WL 4973839 (W.D. La. Oct. 19, 2011) (dismissing claims against generic drug manufacturers after assertion of similar post-*Mensing* arguments by plaintiffs). The court agrees with the preemption analyses contained in those decisions.

35. In short, plaintiff's claims against PLIVA are preempted by federal law. Accordingly, all plaintiff's claims against PLIVA must be dismissed.

II. DECISION AND ORDER

Based on the foregoing, it is hereby ORDERED, ADJUDGED and DECREED that PLIVA's motion to dismiss [doc. 271] is hereby GRANTED and JUDGMENT is entered in favor of PLIVA, Inc., on all claims.

Dated: February 27, 2012.

IT IS SO ORDERED

James C. Mahan

Hon. James C. Mahan
U.S. District Court Judge

Respectfully submitted,

ULMER & BERNE LLP

/s/ Tiffany Reece Clark

TIFFANY REECE CLARK
LINDA E. MAICHL
JOSEPH P. THOMAS
ULMER & BERNE LLP
600 Vine Street, Suite 2800
Cincinnati, Ohio 45202

REX A. LITTRELL
88 East Broad Street, Suite 1600
Columbus, Ohio 43215-3581

DENNIS L. KENNEDY
JOSHUA M. DICKEY
BAILEY❖KENNEDY
8984 Spanish Ridge Ave.
Las Vegas, Nevada 89148

Attorneys for Defendant PLIVA, Inc.